MAY 2 8 2002

Section 12. 510(k) Summary K011461

Submitter's Name and Address: Access CardioSystems
150 Baker Avenue Extension, Suite 108
Concord, MA 01742

Contact Person: David Barash, M.D.
978-371-4985

Device Name: Access CardioSystems Manual Defibrillator

Classification: Low-Energy DC Defibrillator
Class II
21 CFR 870.5300

Predicate Devices:

Zoll M Series Biphasic Defibrillator (K990762)
Physio-Control Biphasic LifePak 500 (K983393)

Indications for Use:

The Access CardioSystems Manual Defibrillator is a manual external defibrillator intended for use for the treatment of ventricular fibrillation in the electrophysiology laboratory. The device is not intended for general clinical use outside the electrophysiology laboratory. The device is not capable of synchronized cardioversion and may only be used for ventricular fibrillation. The device is for adult use only and should only be used by qualified medical personnel.

Device Description:

The Access CardioSystems Manual Defibrillator has been designed specifically for the electrophysiology laboratory. The Access CardioSystems Manual Defibrillator delivers a high-energy 200 or 360J biphasic waveform to patients sustaining ventricular fibrillation in the electrophysiology laboratory.

The Access CardioSystems Manual Defibrillator features include:

- LED ready indicator
- power button
- energy selection button
- charge button
- shock delivery button
- simple electrode adapter cable to be used with standard external defibrillation pads
- disposable Lithium battery system

When ventricular fibrillation is identified in the electrophysiology lab that requires defibrillation, the operator charges the device to the desired energy level (200 J or 360 J). When the device indicates a full charge, the operator delivers the shock by pressing the shock delivery button.

Substantial Equivalence:

The Access CardioSystems Manual Defibrillator is substantially equivalent to other marketed devices delivering a biphasic waveform, specifically the Zoll M Series Biphasic Defibrillator and the Physio-Control Biphasic Lifepak 500. The biphasic waveform in the Access CardioSystems Manual Defibrillator delivers a biphasic waveform with characteristics and results similar to both the predicate devices. The manual operation of this device and any other subtle or minor differences between this device and its predicate devices do not raise any new questions regarding safety and efficacy.

Performance Data:

Performance test data is submitted with the 510 (k) documents. These data demonstrate that the device complies with the applicable sections of AAMI DF2-1996 (Cardiac Defibrillator Devices). The device was developed under design control, and the hardware was tested in accordance with established industry standards.

The efficacy of the biphasic truncated exponential waveform in this device was demonstrated in a study of swine. The results of this study demonstrates the substantial equivalence of the Access CardioSystems Manual Defibrillator biphasic truncated exponential waveform. Though there are minor differences in the characteristics of the Access CardioSystems Manual Defibrillator biphasic waveform and its predicate device waveforms, these differences do not raise new questions of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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David Barash, M.D.
Access CardioSystems
150 Baker Avenue Extension, Suite 108
Concord, MA 01742

Re: K011461
Access CardioSystems Manual Defibrillator
Regulation Number: 870.5300
Regulation Name: DC-Defibrillator Low Energy (Including Paddles)
Regulatory Class: II (two)
Product Code: LDD
Dated: February 26, 2002
Received: February 27, 2002

Dear Dr. Barash:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

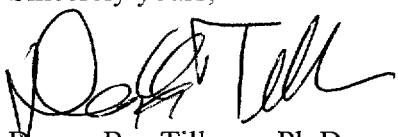
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011461

Device Name: Access CardioSystems Manual Defibrillator

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011461

Prescription Use X
(Per 21 CFR 801.109)

(Optional Format 3-10-98)